#### ORAL COMPOSITION

## BACKGROUND OF THE INVENTION

### 1. Industrial Field

The present invention relates to an oral composition which comprises triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) and more particularly, to an oral composition wherein the lowering in activity of triclosan by surface active agents can be prevented and the germi- 10 cidal activity of triclosan is shown to a satisfactory extent.

#### 2. Prior Art

It is known that oral compositions such as dentifrice which comprise triclosan as an effective ingredient can 15 inhibit the formation of dental plaque because of the intense germicidal action of triclosan. In fact, there has been proposed incorporation, in oral compositions comprising triclosan, of zinc salts (Japanese Laid-open Patent Application Nos. 60-239409 and 3-127719, and <sup>20</sup> Japanese Patent Publication No. 64-10489), copper compounds (Japanese Laid-open Patent Application No. 62-89614), polyethylene glycol (Japanese Laidopen Patent Application No. 62-126116), and the like.

However, when triclosan and a surface active agent 25 such as alkyl sulfates ordinarily used as a foaming agent are used in combination, the germicidal activity is considerably lowered, with the problem that the effect of triclosan is not shown satisfactorily. In order to solve this problem, the present applicant already proposed 30 the formulation of phenolic compounds (Japanese Laidopen Patent Application No. 2-11511) or water-soluble calcium salts (Japanese Laid-open Patent Application No. 3-5416) in an oral composition which comprises triclosan and a surface active agent. More effective 35 measures for the dissolution are desirable.

It is essential to add a surface active agent to an oral composition such as dentifrice in order to make foams on use and to improve the feel in use. In particular, alkyl sulfates which are anionic surface active agents are most 40 widely employed for this purpose. However, it presents a serious problem that triclosan which is added to oral compositions is impeded in activity by means of surface active agents. There is a demand of inhibiting the lowering in the activity of triclosan by surface active agents. 45

# SUMMARY OF THE INVENTION

An object of the present invention is to provide an oral composition containing triclosan in combination with an alkyl sulfate in which triclosan can be stably 50 formulated to exert its effect, thereby preventing the formation of dental plaque and the occurrence of gingi-

We made intensive studies and, as a result, found that when a water-soluble tin salt is added to an oral compo- 55 sition which comprises triclosan and an alkyl sulfate surface active agent, the triclosan can be stably formulated in the composition comprising the alkyl sulfate surface active agent whereby the germicidal activity of triclosan can be effectively inhibited from lowering and 60 tion, the oral composition of the invention may further shows its intense germicidal activity effectively.

As will become apparent from experiments described later, such an effect as set forth above is not produced when sparingly soluble or insoluble tin salts such as stannous pyrophosphate are added to oral compositions 65 which comprise both triclosan and alkyl sulfates, but is developed only when water-soluble tin salts are added. Moreover, any stable composition is not obtained when

water-soluble tin salts are added to triclosan and alkyl ether sulfates. Unexpectedly, we have found that when trichlosan, alkyl sulfates and water-soluble salts are used in combination, triclosan is stabilized. The invention is accomplished based on the finding that the stabilization of trichlosan results from a combination of these three ingredients.

It is known to formulate either alkyl sulfate surface active agents or water-soluble tin salts to triclosan-containing oral compositions (Japanese Laid-open Patent Application Nos. 62-89614 and 3-127719). Nevertheless, it is our finding that when triclosan, an alkyl sulfate surface active agent an a water-soluble tin salt are used in combination, a significant synergistic effect is obtained.

Therefore, according to the present invention, there is provided an oral composition comprising triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether), an alkyl sulfate and a water-soluble tin salt.

## DETAILED DESCRIPTION OF THE **INVENTION**

The oral composition of the invention may be used in the form of dentifrices such as toothpastes, toothpowders and liquid dentifrices, mouthwashes, gingiva-massage creams, liquid or paste regional ointments, troches, chewing gums and the like. The composition comprises, in combination, triclosan, an alkyl sulfate surface active agent and a water-soluble tin salt.

The amount of triclosan is not critical and is generally in the range of 0.001 to 1.0% by weight, preferably 0.01 to 0.5% by weight of the total weight of the oral com-

The alkyl sulfate used as the surface active agent is one whose carbon chain has 8 to 18 carbon atoms, preferably 10 to 14 carbon atoms. Specific examples of the alkyl sulfate surface active agent include sodium lauryl sulfate, sodium myristyl sulfate and the like.

The amount of the alkyl sulfate is not critical and generally in the range of 0.01 to 10% by weight, preferably 0.1 to 5% by weight of the total weight of the composition.

The water-soluble tin salts may be either inorganic or organic so long as they can be formulated from the pharmaceutical standpoint. Specific examples include stannous fluoride, stannous chloride, stannous fluoride chloride, stannous acetate, stannous sulfate, stannous tartrate, stannous gluconate, stannous citrate and the like. Of these, stannous fluoride stannous chloride and stannous gluconate are preferred.

The amount of the water-soluble tin salt is not critical and is generally in the range of 0.01 to 10% by weight, preferably 0.1 to 2% by weight of the total weight of the composition. If the amount is less than 0.01% by weight, the lowering in the activity of triclosan in the composition may not be prevented. Over 5% by weight, the feel of the composition may be impeded.

Depending on the purpose and the type of composicomprise, aside from the above-stated ingredients, abrasives, binders, humectants, flavors and other effective ingredients in amounts not impeding the germicidal effect of triclosan.

Examples of the abrasive include calcium hydrogen phosphate dihydrate, calcium carbonate, calcium pyrophosphate, calcium sulfate, insoluble sodium metaphosphate, silicic anhydride, hydrous silicic acid, aluminosil-